

REMARKS/ARGUMENT

Per the petition and fee submitted herewith, Applicants invoke the benefit of 37 CFR 1.136 to secure a one-month extension of time up to and including December 22, 2003. Please charge any further fees due, or credit any overpayment, to deposit account no 50-0573. Based on the above changes and the following remarks, Applicants respectfully request reconsideration of the pending claims.

Applicants' representative thanks Examiner Gina Wu and Examiner Sreeni Padmanabhan for the telephonic interview conducted on December 9, 2003.

Claim 1-5, 7, 8, 11 and 22-28 are pending in the application. Claims 1, 4, 11, 22 and 23 have been amended. In Claim 1, the spelling of "foamable" has been corrected. In Claim 11 the term "formulation" has been amended to "foamable gelling agent" to ensure proper antecedent basis. Support for the amendment to claim 11 is found in claim 1 as originally filed. In Claims 22 and 23 the word "treated" has been introduced to clarify that it is the treated foam which is washed or oven dried. Support for the amendment to claim 22 is found on pg. 9, lns. 17-20 of the specification. Support for the amendment to claim 23 is found on pg. 9, lns. 27-29 of the specification.

Rejection under 35 U.S.C. 112, 2nd paragraph

Claim 4 is rejected under 35 U.S.C. 112, 2nd paragraph because the term "carboxymethyl-cellulose" allegedly lacks antecedent basis. The term "carboxymethyl-cellulose" has been deleted from claim 4 to overcome the Examiner's rejection.

Rejections under 35 U.S.C. 103(a)

Claims 1 to 5, 7 to 8, 11 and 25-27 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Bakis (US 5,851,461) in view of Gilchrist (WO 96/17595). Applicant contends that the Examiner is incorrect in this conclusion for the reasons discussed below.

Claim 1 requires the use of two precipitants. The first precipitant is applied before or

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during foaming, and a second precipitant is applied after curing of the foam. Examiner states that Bakis discloses a method which incorporates a first and a second cross-linking (precipitating) step. Applicant respectfully points out that this is not the case. In each example of Bakis, the foam is subjected to only one cross-linking step. Gilchrist also does not teach a second precipitation step prior to sterilising the foam. Moreover, neither Bakis nor Gilchrist suggest that subjecting the foam to a first and a second cross-linking step prior to sterilisation would be desirable.

The Examiner refers on page 3 of the Office Action to exemplification within Bakis and cites column 8, lines 15 to 59 and column 10, line 20 to column 11 line 34. The Examiner states that a sodium alginate and sodium dodecyl sulphate solution is beaten with a mixer to produce a foam, and which is then spread on a metal tray and cross-linked with an aqueous solution containing calcium chloride. The foam was then dried. It is believed that the Examiner is referring here to the steps described in Example 1 of Bakis. However, the Examiner then mistakenly reads Example 2 to understand that it is the cross-linked dried foam of Example 1 which is used as a starting material for Example 2. This is erroneous, but is due to the failure of Bakis to expressly distinguish between the newly produced foam of Example 1 (referred to in column 8, line 22) and the cross-linked dried foam (referred to in column 8, line 30).

The Examiner's assumption that the cross-linked dried foam of Example 1 is referenced as a starting material of Example 2 is clearly in error. Example 2 refers to a mesh fabric being used "as a substrate for a layer of alginate foam as described in Example 1". The wording clearly only refers to a similar type of foam and methodology as described in Example 1 prior to cross-linking, and does not make reference to the actual cross-linked foam product of Example 1; hence the use of the indefinite article "a" in relation to "a layer of alginate foam" rather than an explicit reference to the foam of Example 1. Example 2 also states that the "foam was spread on the fabric"; it would not be possible to "spread" a cross-linked dried foam pad produced as described in Example 1 on a fabric, nor would the subsequent steps described in Example 2 lead to such a dried foam pad becoming "adhered to the gauze pad".

Moreover, the dried foam pad of Example 2 is converted to a more water soluble

form by immersing the pad in an HCl solution. The converted foam pad is made more water soluble due to the replacement of the cross-linking di- or tri-valent cations with monovalent cations (see also col. 4, lns. 49-65 of Bakis). Breakage of the cross-links with HCl is confirmed in Example 2 by inducing gelation of the foam with sodium citrate. If the ultimate result of Example 2 is to produce a water-soluble (*i.e.*, non cross-linked) foam, it would not make sense to cross-link the foam a second time before conversion. Thus, the wording and results of Example 2 are logical only if the reference to "foam" is read to refer to a newly produced, non-cross-linked foam.

One skilled in the art would therefore read Examples 1 and 2 of Bakis to represent alternative ways of making foam-covered substrates, where the foam is subjected only to a single cross-linking step. One skilled in the art would not read Examples 1 and 2 of Bakis to be sequential, especially because the foam pad ultimately produced in Example 2 has reduced cross-linking. Indeed, the only post-cross-linking step described in Bakis which entails immersion of the foam in a solution is the "conversion" of the foam to a more water soluble form. Applicant therefore submits that Bakis does not disclose or suggest a second cross-linking step by immersion of the foam in a precipitant bath, as is required in the present claims.

Example 10 of Bakis discloses a method where there is a first treatment with calcium chloride and a further treatment with sodium chloride. The treatment with sodium chloride is not, however, a cross-linking (precipitating) step. Cross-linking of alginate is dependent on using a multivalent cation; *e.g.*; a Group 2 or 3 metal ion (see Bakis column 4, lns. 25 to 33). Sodium is a Group 1 metal and forms a monovalent cation (Na^+) when in solution. Thus treatment of the alginate foam with sodium chloride cannot constitute a second cross-linking step. Bakis does not describe a second cross-linking step as required in Claim 1 and does not recognise the benefits conferred by cross-linking following cure of the foam.

The foam produced according to the method of Claim 1 has improved stabilization and therefore resistance to damage caused by sterilization. This is a result of the second precipitation step which is absent from Bakis. As discussed in the present Application (page 8, lines 16 to 21) referring to the prior art foams of Gilchrist, performing the sterilization step on the prior art foam causes destruction of the foam structure. The sterilization step referred

to by the Examiner in Gilchrist is performed on the gelling agent prior to foaming. This is in contrast to the present invention where the sterilizing step occurs on the foam itself. At page 9, lines 1 to 22 of the present Application it is clearly stated that the additional precipitation step is advantageous as it further stabilizes the foam thus allowing sterilization without damage. This is not disclosed nor suggested in Gilchrist or Bakis. The beneficial effects of performing a second precipitation step in stabilizing the structure are surprising, as one of ordinary skill in the art would not expect that repeating an already performed step would significantly improve the stability of the foam. Also, as discussed above, the "conversion" step shown in Bakis Example 2 teaches away from subjecting the foam to a second cross-linking step.

Furthermore, the ability to sterilise the foam in its finished state is extremely significant as it allows production of a sterile finished product, without the costly need for ensuring all steps of production are conducted in sterile conditions.

Claim 1 also requires that the first precipitant is combined with the gelling agent before or during the formation of the foam. This is not the case in Bakis. Example 3 of Bakis does mention the inclusion of calcium carbonate in a sodium alginate solution prior to mixing. However, calcium carbonate is an insoluble salt and does not release calcium ions, which are essential for precipitation. The precipitation step in this example only occurs after foaming, upon application of a strong acid. Thus calcium carbonate cannot be considered a precipitant as it is insoluble and therefore cannot cause precipitation. It only becomes a precipitant when calcium ions are caused to be released by application of a strong acid; *i.e.*, HCl at 0.1N.

It is further respectfully pointed out that hydrochloric acid is an inorganic acid, and therefore Bakis does not teach inclusion of an organic acid as claimed in Claim 11. In addition the HCl is only applied after foaming and therefore no acid at all is taught as being part of the "foamable gelling agent".

Thus, contrary to the Examiner's conclusions, Bakis and Gilchrist, either alone or in combination, do not suggest the method of Claim 1 or provide one of ordinary skill with a reasonable expectation that stabilised foams can be successfully produced from the method of Claim 1. Indeed, the method of Claim 1 has significant and surprising advantages over

those disclosed in Bakis with regard to stability, sterility and homogeneity of the foam produced.

The Applicant contends that Claim 1 is non-obvious over the disclosures of Bakis in view of Gilchrist. Claims 5, 7 to 8, 11 and 25-27 all depend directly or indirectly from Claim 1. Therefore, these claims are also non-obvious over Bakis or Gilchrist, either alone or in combination, for the reasons outlined above.

Claim 22 is rejected as allegedly rendered obvious by Bakis and Gilchrist further in view of U.S. Pat. No. 5,641,450 to Kobayashi. Bakis and Gilchrist are discussed above. Kobayashi discloses the use of a water/glycerine wash to prevent drying of a foam. Kobayashi does not disclose or suggest a method of producing a sterile foam using two separate precipitant steps. Kobayashi therefore does not provide the missing teachings from Bakis and Gilchrist, and these three references, either alone or in combination, cannot render Claim 22 obvious.

Claim 23 is rejected as allegedly rendered obvious over Bakis and Gilchrist further in view of U.S. Pat. No. 4,201,846 to Kehr et al. (Kehr). Bakis and Gilchrist are discussed above. Kehr discloses microwave, oven and air drying of a foam. However, Kehr relates to hydrocarbon polymer foams for use in household situations. This is a significantly different field of technology from that of the present invention; *i.e.*, physiologically acceptable foams for medical or veterinary use, and indeed to the foams as disclosed in Bakis or Gilchrist which are liable to collapse if treated by such processes. Moreover, Kehr does not disclose or suggest a method of producing a sterile foam using two separate precipitant steps.

It is respectfully pointed out that a foam which has not been stabilized by a second precipitation step is prone to collapsing under harsh conditions. The oven drying in the present Claim 23 is performed on the treated foam, which is stabilized by the two precipitation steps and is therefore more able to withstand the harsh environment of an oven. Kehr therefore does not provide the missing teachings from Bakis and Gilchrist, and these three references, either alone or in combination, cannot render Claim 23 obvious.

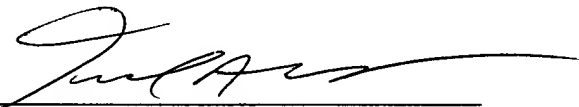
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Claims 24 and 28 are rejected as allegedly obvious over Bakis and Gilchrist further in view of U.S. Pat. No. 4,693,728 of Clare et al. (Clare). Bakis and Gilchrist are discussed above. Clare discloses that the use of a sparingly soluble salt, such as calcium citrate, with sodium alginate into can be used to control release of calcium into the alginate. Clare does not disclose or suggest production of a stabilised foam by employing two precipitant steps. Clare therefore does not provide the missing teachings from Bakis and Gilchrist, and these three references, either alone or in combination, cannot render Claims 24 and 28 obvious.

Applicant believes that the Application as currently amended is in condition for allowance, and notification to that effect is earnestly solicited.

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